Translation

PCT Application
PCT/JP2003/004247

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

12 OCT 2004

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-15	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/004247	International filing date (*day/month/year*) 03 April 2003 (03.04.2003)	Priority date (*day/month/year*) 09 April 2002 (09.04.2002)

International Patent Classification (IPC) or national classification and IPC
A61K 7/00, 7/04, 7/06, 7/48, 31/7072, 31/7076, A61P 17/02, 43/00

Applicant OTSUKA PHARMACEUTICAL CO., LTD.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have b amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see I 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicab citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 18 August 2003 (18.08.2003)	Date of completion of this report 04 December 2003 (04.12.20
Name and mailing address of the IPEA/JP	Authorized officer Telephone No.

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I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 10-20, 22-33, 36-37

because:

☒ the said international application, or the said claims Nos. 10-20, 22-33, 36-37 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Provided the composition of this application is utilized for the treatment of wounds, the inventions of claims 22-33 correspond to a "method for treatment of the human body by therapy" (PCT Rule 67.1 (iv)).

In addition, the process for producing the inventions of claims 10-20, 36, and 37 is not specified, and as a result these inventions are also included in the therapeutic process. Therefore, the above reasoning also applies to these inventions.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 10-20, 22-33, 36-37 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3, 9, 21, 34, 38	YES
	Claims	1-2, 4-8, 35	NO
Inventive step (IS)	Claims		YES
	Claims	1-9, 21, 34-35, 38	NO
Industrial applicability (IA)	Claims	1-9, 21, 34-35, 38	YES
	Claims		NO

2. Citations and explanations

Documents 1 and 2 below were cited in the international search report.

Document 1: WO 98/32429 A2 (The University of Liverpool)
Document 2: EP 360882 A1 (Crinos Industria Farmacobiologica S. p. A.)

Document 1 states that wound healing and improvement in the condition of the skin can be seen by stimulating the intracellular release of ATP with a P2 receptor agonist and promoting the growth of keratinocytes, and it lists AMP, UMP, and the like as agonists.

Although the above document does not specifically disclose the combined use of AMP and UMP, it discloses that an enhanced is seen with the combined use of another agonist (ADP or ATP) and a growth factor. Therefore, an enhanced effect can obviously be predicted with the combined use of the above agonists.

Document 2 discloses that a composition containing depolymerized DNA (adenine 8 to 10%, guanine 7 to 9.5%, cytosine 5.5 to 7.5%, thymine 8 to 11%), i.e., a topical composition containing a purine nucleic acid-related substance and a pyrimidine nucleic acid-related substance, has hair stimulating, anti-dandruff and anti-seborrhoic activity. However, document 2 does not specifically disclose a composition in which adenylic acid and uridylic acid have been isolated and combined.